

# PATENT COOPERATION TREATY

1 JAN 2005

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

<b>To:</b>  <b>GILL JENNINGS &amp; EVERY</b> Broadgate House 7 Eldon Street London EC2M 7LH GRANDE BRETAGNE	<b>RECEIVED</b>  <b>5 AUG 2004</b>  <b>GILL JENNINGS &amp; EVERY</b>
---	--

**DIARIED**  
**PCT**  
**WRITTEN OPINION**  
**(PCT Rule 66)**

Date of mailing (day/month/year) <b>04.08.2004</b>	
Applicant's or agent's file reference <b>MJB07161WO</b>	<b>REPLY DUE</b> <b>within 2 month(s) (two)</b> from the above date of mailing
International application No. <b>PCT/GB 03/03139</b>	International filing date (day/month/year) <b>18.07.2003</b>
Priority date (day/month/year) <b>19.07.2002</b>	
International Patent Classification (IPC) or both national classification and IPC <b>B65D83/14</b>	
Applicant <b>THE TECHNOLOGY PARTNERSHIP PLC</b>	


- This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
- This opinion contains indications relating to the following items:
  - ☒ Basis of the opinion
  - ☐ Priority
  - ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☒ Lack of unity of invention
  - ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Certain documents cited
  - ☐ Certain defects in the international application
  - ☐ Certain observations on the international application
- The applicant is hereby invited to reply to this opinion.
 

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:** For an additional opportunity to submit amendments, see Rule 66.4.  
 For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
 For an informal communication with the examiner, see Rule 66.6.

**If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
- The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **19.11.2004**

Name and mailing address of the international preliminary examining authority:   <b>European Patent Office - P.B. 5818 Patentlaan 2</b> <b>NL-2280 HV Rijswijk - Pays Bas</b> <b>Tel. +31 70 340 - 2040 Tx: 31 651 epo nl</b> <b>Fax: +31 70 340 - 3016</b>	Authorized Officer <b>Fournier, J</b> Formalities officer (incl. extension of time limits) <b>Micheli, M</b> Telephone No. +31 70 340-3606
---	--



**I. Basis of the opinion**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

**Description, Pages**

1-9 as originally filed

**Claims, Numbers**

1-14 as originally filed

**Drawings, Sheets**

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

**IV. Lack of unity of invention**

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☒ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- ☒ all parts.
- ☐ the parts relating to claims Nos. .

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1 2 7 10
Inventive step (IS)	Claims	12
Industrial applicability (IA)	Claims	

2. Citations and explanations

**see separate sheet**

**Re Item IV**

**Lack of unity of invention**

This international application does not comply with the requirement of unity of invention (Rule 13.1, 13.2, 13.3) because it comprises two inventions, invention I (claims 1-12) and invention II (claims 13-14).

Invention I (claims 1-12) relates to a valve mechanism comprising a first and a second valve mechanism for use in an inhaler comprising a pressurised container and a metering chamber. Claim 12 relates to an inhaler mechanism incorporating a valve mechanism according to any of the claims 1-11, connected to a pressurised container.

Invention II (claims 13-14) relates to a method of manufacturing an inhaler according to claim 12.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Reference is made to the following documents:**

D1: US-A-3052382

D2: US-A-2 974 453

**2. Examination: INVENTION I, claims 1-12:**

**2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 2 is not new in the sense of Article 33(2) PCT.**

D1 discloses a valve mechanism suitable for use in an inhaler comprising a pressurised container and a metering chamber, the valve mechanism comprising: a first valve member (2) arranged to be positioned between the pressurised container and the metering chamber, the first valve member (2) being movable between a closed position in which the container is closed (see figure 1), and an open position in which the container is open to the metering chamber (see figure 2), the first valve member (2) being biased to remain in the first position by the pressure in the container and a return spring (8); and a second valve member movable between a rest position in which the metering chamber is closed (see figure 1), a metering position in which the second valve member actuates the opening of the first valve member (2) to enable a metered dose to be dispensed into the metering chamber (see figure 2), and an open position in which the metering chamber is open to allow medicament to be inhaled (see figure 4).

As all the technical features of claims 1 and 2 are known from D1, the subject-matter of each of these claims is not new.

**2.2 Dependent claims 7 and 10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, see document D1, figures 1-4.**

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 12 does not involve an inventive step in the sense of Article 33(3) PCT.

Incorporating a valve mechanism according to claim 1 to an inhaler is one of several possible uses of such a valve mechanism and therefore the subject-matter of claim 12 cannot be considered as involving an inventive step.

4. The combination of the features of dependent claims 3-6, 8-9 and 11 is neither known from, nor rendered obvious by, the available prior art. It is suggested therefore that a new independent claim be drafted to include one of these features, bearing in mind that the features known in combination in D1 should be placed in the preamble of such a claim.

**5. Examination, INVENTION II, Claims 13 and 14:**

**5.1 Claim 13:**

**Nearest prior art: D2**

D2 discloses a method of pressure filling an aerosol container. It comprises the steps of:

providing a container (10) to be pressurised closed by a first valve (16, 17);  
inserting a material into the container (10) through the first valve (16, 17);  
pressuring the container with propellant through the first valve and  
attaching a stem.

**Problem:**

In order to vary the volume dispensed, i.e the volume of the metering chamber, the concentration of the medicament supplied to the container has to be varied.

**Solution:**

Attaching a second valve to form the metering chamber after the inserting and pressuring steps. With this method, a number of different metering chamber volumes can be achieved using the same size container and first valve. The available prior art teaches away from this solution, by forming the metering chamber prior to the filling step. The subject-matter of claim 13 is therefore new (Article 33(2) PCT) and is considered as involving an inventive step (Article 33(3) PCT).

- 5.2 Claim 14 is dependent on claim 13 and as such also meet the requirements of the PCT with respect to novelty and inventive step.